REMARKS

Claims 1-14 and 17-43 are currently pending in the application. Claims 15-16 were canceled in the "Amendment and Reply" filed September 17, 2003. Claims 1-2 are amended, and are supported by the sequence listing. New claims 40-43 are presented, and are supported by the sequence listing and by paragraph 15 of the specification. No new matter is added. Reconsideration and further examination is requested.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-2 and 4-39 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while being enabling for a polynucleotide having the function of a replicon, does not reasonably provide enablement for using any polynucleotide comprising a polynucleotide having a sequence at least 95% identical to SEQ ID NOs:1, 3 or 4.

Applicant has amended claims 1 and 2 to recite an isolated nucleic acid molecule having the sequence of the nucleotide sequence of a *Ketogulonigenium* plasmid replicon found on the endogenous plasmid contained in Deposit No. NRRL B-30035 (claim 1) and the replicon as shown in SEQ ID NO:1 (claim 2). Applicant respectfully requests that the rejection on this basis be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-2 and 4-39 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in such a way as to reasonably convey possession of the invention.

As discussed above, claims 1 and 2, from which claims 4-39 depend, have been amended. Applicant therefore respectfully requests that the rejection on this basis be reconsidered and withdrawn.

Claims 1, 6-8, 10, 31 and 35-36 are also rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in such a way as to reasonably convey possession of the invention. The Office Action states that "[t]he specification does not contain any disclosure of the structure of all DNA sequences comprising the above bacterial replicons,

temperature sensitive replicons, expression control sequence, terminator sequence, ribosome binding site" (Office Action, page 6).

The subject matter of the claims is fully supported by the specification. For instance, mob sites are discussed at paragraph 39. The incompatibility groups of claim 9 are also discussed at paragraph 39. Other organisms that can be used in the invention are discussed at paragraphs 48, 53 and 56. Temperature-sensitive replicons are discussed at paragraph 10. Marker genes and reporter genes, including antibiotic-resistance genes, are discussed at paragraphs 36, 44 and 45. Paragraphs 27 and 40 discuss polylinkers, terminator sequences and ribosome binding sites. His-tag sequences are discussed at paragraph 29. Expression control sequences are discussed at paragraphs 40 and 42. Paragraph 40 discusses both signal peptides and cos sites, which are also discussed at paragraph 34. The pET, pUC18 and pUC 19 plasmids are discussed at paragraph 48.

There is no requirement that Applicant disclose the DNA sequences making up these replicons, and expression, termination and ribosome binding sequences, etc. Such sequences and their use in the engineering of vectors are known to those of ordinary skill in the art. There is no need to recite sequences that are known to the public.

The Office Action refers Applicant to the Written Description Guidelines. These Guidelines state that "the 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." (at 1104, quoting *In re Barker*, 599 F.2d 588, 592 n. 4, 194 U.S.P.Q. 470, 473 n. 4 (C.C.P.A. 1977)). The Guidelines describe precisely how the determination is to be made:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. [citing *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971)] The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. [citing *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976)] In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis

> which support the lack of written description conclusion. These findings should:
>
> (1) Identify the claim limitation at issue; and
>
> (2) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

(at 1107, second and third columns).

The claims do not attempt to protect the promoters, expression sequences, etc., but rather, the sequences of SEQ ID NOs: 1, 3 and 4 in a vector combined with promoters, expression sequences, etc. Many promoters, terminators, etc. have been isolated, and their sequences are known and are publicly available, often from commercial suppliers. The Office Action has not set forth any objective reasons why one of ordinary skill in the art would not recognize that applicants were in possession of vectors containing SEQ ID NOs: 1, 3 and 4 in combination with publicly-available promoters, terminators, signal sequences, etc. Literal description of all embodiments or all members of a genus is not necessary to satisfy the written description requirement of 35 U.S.C. § 112.

In the absence of a preponderance of evidence or reasoning why a person skilled in the art would not recognize in Applicant's specification a description of the invention defined by the claims, the rejection on this basis must be withdrawn.

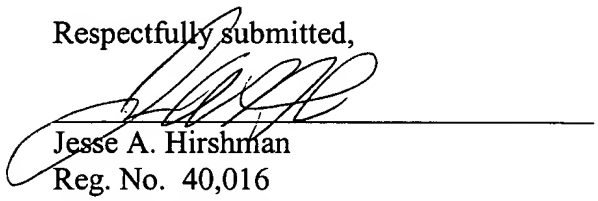
Double Patenting

Claims 1-39 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Pat. No. 6,503,748.

Applicant respectfully submits that the present claims, as they pertain to SEQ ID NOs: 3 and 4, are not obvious in view of U.S. Pat. No. 6,503,748. However, a terminal disclaimer will be filed in the present case upon an indication of allowable subject matter.

Applicant believes that claims 1-14 and 17-43 define over the prior art of record and are in proper form for allowance. Applicant respectfully requests allowance of claims 1-14 and 17-43.

Respectfully submitted,



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